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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/581,511

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7590

08/21/2006

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EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/581,511	<b>Applicant(s)</b> ANDERSEN ET AL.	
	<b>Examiner</b> David Lukton	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23-25,27,29,31-66 and 68-78 is/are pending in the application.
- 4a) Of the above claim(s) 24,27,29,34,36,59,60,62 and 74 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 35,37-58,61,63-66 and 68-72 is/are allowed.
- 6) ☒ Claim(s) 23,25,31-33,73 and 75-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Pursuant to the directives of the amendment filed 5/30/06, several claims have been amended. Claims 23-25, 27, 29, 31-66, 68-78 remain pending. Claim 74 remains withdrawn from consideration pursuant to the original restriction. Claims 24, 27, 29, 34, 36, 59, 60, 62 are withdrawn from consideration, since they do not encompass the elected specie. The following claims are examined in this Office action: 23, 25, 31-33, 35, 37-58, 61, 63-66, 68-73, 75-78.

Applicants' arguments filed 9/14/05 have been considered and found persuasive in part. For purposes of this Office action, the characterization of "allowable" is applied to each of the following claims: 35, 37-58, 61, 63-66, 68-72.

Applicants have argued that claim 36 should not be withdrawn. However, this claim does not encompass the elected specie. Applicants are advised that a characterization of a given claim as allowable in one Office action no more precludes rejection of that claim in a subsequent Office action, than does rejection of a claim in one Office action preclude allowance of that claim in a later Office action.



The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

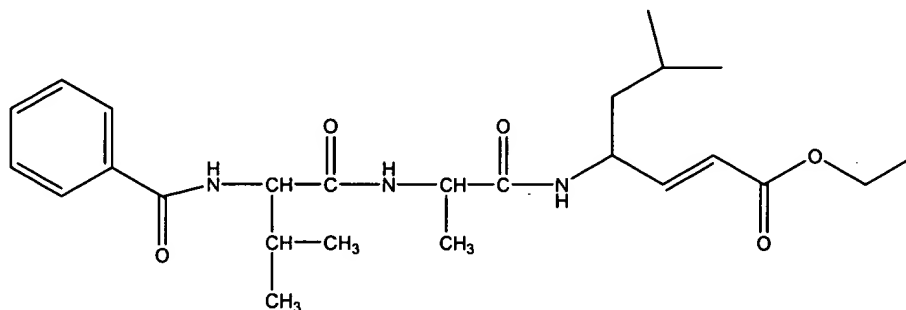
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23, 25, 31-33, 73, 76 are rejected under 35 U.S.C. §102(a) as being anticipated by Johnson (WO 97/04004).

As indicated previously, Johnson discloses compound 26 (page 74), which has the following structure:



This compound is encompassed by the claims when the substituent variables are as follows:

- R1 = benzoyl;
- R2 = hydrogen;
- R3 = methyl;
- R4 = methyl;
- R5 = hydrogen;

R6 = hydrogen  
R7 = methyl  
R8 = hydrogen  
Y = propylene substituted with isobutyl  
Z = -O-CH<sub>2</sub>-CH<sub>3</sub>

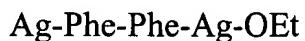
In response, applicants have argued that the claims exclude the possibility that R<sub>3</sub> or R<sub>4</sub> can be methyl when R<sub>2</sub> is hydrogen. However, applicants are incorrect. There is no such exclusion. If applicants would like to introduce such an exclusion, this is certainly an option; the exclusion, however, should be made clear and unmistakable.

Thus, the claims are anticipated.



Claim 23 is rejected under 35 U.S.C. §102(b) as being anticipated by Falender (*Biocatalysis and Biotransformation* 13(2), 131-139, 1995).

As indicated previously, Falender discloses the following compound on page 134 ("Ag" represents allylglycine):



The disclosed compound is encompassed by the claims when the substituent variables are as follows:

R1 = allylglycine;  
R2 = hydrogen;  
R3 = phenyl;  
R4 = hydrogen;  
R5 = hydrogen;

R6 = hydrogen;  
R7 = benzyl;  
R8 = hydrogen;  
Y = butene;  
Z = -O-CH<sub>2</sub>-CH<sub>3</sub>

Substituent variable R<sub>1</sub>, as indicated above, can be allylglycine. That is, the claim permits R<sub>1</sub> to be a C<sub>5</sub>-unsaturated alkyl group which is substituted once with oxo, and once with amino. If R<sub>5</sub> were phenyl, then perhaps R<sub>1</sub> could not be substituted with oxo, but the point is moot since R<sub>5</sub> is hydrogen.

Thus, the claim is anticipated.



Claims 75, 77, 78 are rejected under 35 U.S.C. §102(e) as being anticipated by Eisenbach-Schwartz (USP 6,126,939).

Eisenbach-Schwartz discloses (col 3, line 56) the following tripeptide: Glu-Arg-Ala.

R7 = the side chain of arginine  
R5 = -CH<sub>2</sub>-COOH;  
R1 = hydrogen  
R2 = hydrogen  
Y = ethyl;  
Z = OH

As indicated previously, claim 75 does not require "Y" to be an "unsaturated alkyl" group. Claim 75 permits variable R<sub>9</sub>, together with the nitrogen atom to which it is bonded, to be a genetically encoded amino acid; that is, "Y" can be a "saturated moiety

having a linear or branched...skeleton containing 1-10 carbon atoms". Thus, variable R<sub>9</sub> could represent Ala, Gly, Leu, Ile, Val, Ser, or Thr. As such, claim 75 encompasses numerous tripeptides that have been previously disclosed.

In response to the foregoing, applicants have pointed to the phrase at issue, and have argued that it should be interpreted differently. The phrase at issue is the following:

"Y is a linear, unsaturated, two to six carbon alkyl group, optionally substituted with phenyl, naphthyl, anthracyl, phenanthryl or a saturated or unsaturated moiety having a linear, branched, or non-aromatic cyclic skeleton consisting of one to ten carbon atoms optionally substituted with =S or -OH"

Applicants have argued that the way the phrase should be interpreted is that "Y" is an unsaturated alkyl group which is optionally substituted with a saturated moiety, and not that "Y" can be a saturated moiety. The examiner disagrees. The more reasonable interpretation is the one below, wherein the implied phrase "else Y is" has been inserted:

"Y is a linear, unsaturated, two to six carbon alkyl group, optionally substituted with phenyl, naphthyl, anthracyl, phenanthryl,  
or **else Y is** a saturated or unsaturated moiety having a linear, branched, or non-aromatic cyclic skeleton consisting of one to ten carbon atoms optionally substituted with =S or -OH"

Of course, the phrase "else Y is" is not present in the claim, but its presence is implied.

If applicants genuinely believe that the claim should be interpreted as asserted, applicants should feel no reluctance in making this more clear. Following is one option

(substituent variable "G" has been created for purposes of illustration):

"Y is a linear, unsaturated, two to six carbon alkyl group, optionally substituted with G;

wherein G is phenyl, naphthyl, anthracyl, or phenanthryl;

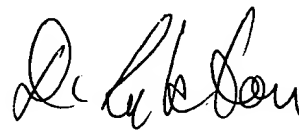
or G is a saturated or unsaturated moiety having a linear, branched, or non-aromatic cyclic skeleton consisting of one to ten carbon atoms optionally substituted with =S or -OH"

Another possibility would be the following:

"Y is a linear, unsaturated, two to six carbon alkyl group, optionally substituted with phenyl, naphthyl, anthracyl, phenanthryl;

or Y is a linear, unsaturated, two to six carbon alkyl group which is optionally substituted with a saturated or unsaturated moiety having a linear, branched, or non-aromatic cyclic skeleton consisting of one to ten carbon atoms optionally substituted with =S or -OH"

As the claims stand, however, they remain anticipated.



DAVID LUKTON, PH.D.  
PRIMARY EXAMINER

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.